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PCT/US99/09486

What is claimed is:

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- 1. A vaccine composition comprising an isolated and purified recombinantly-expressed pilin protein of the genus *Neisseria*, wherein said vaccine composition elicits a protective immune response in a human host.
- 2. The vaccine composition of Claim 1 where the pilin protein is from the species Neisseria gonorrhoeae.
- 3. The vaccine composition of Claim 1 where the pilin protein is from the species Neisseria meningitidis.
- The vaccine composition of Claim 3 where the pilin protein is the class I pilin protein of Neisseria meningitidis.
- 5. The vaccine composition of Claim 3 where the pilin protein is the class II pilin protein of Neisseria meningitidis.
- 6. The vaccine composition of Claim 1 where the pilin protein is a chimeric recombinant pilin protein of Neisseria gonorrhoeae and class I Neisseria meningitidis having the amino acid sequence of amino acids 1-167 of SEQ ID NO:2 prior to processing or having the amino acid sequence of amino acids 8-167 of SEQ ID NO:2 after processing to a mature protein, or a biologically equivalent amino acid sequence thereof.
- 7. The vaccine composition of Claim 1 which further comprises an adjuvant, diluent or carrier.
- 8. The vaccine composition of Claim 7 wherein the adjuvant is selected from the group consisting of aluminum hydroxide, aluminum phosphate, Stimulon™ QS-21, 3-O-deacylated monophosphoryl lipid A, IL-12 and wild-type or mutant cholera toxin.

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- 9. A method of immunizing against Neisseria gonorrhoeae which comprises administering to a human host an immunogenic amount of the vaccine composition of Claim 2.
- 10. A method of immunizing against Neisseria gonorrhoeae which comprises administering to a human host an immunogenic amount of the vaccine composition of Claim 3.
- 11. A method of immunizing against Neisseria gonorrhoeae which comprises administering to a human host an immunogenic amount of the vaccine composition of Claim 6.
- 12. A method of immunizing against Neisseria meningitidis which comprises administering to a human host an immunogenic amount of the vaccine composition of Claim 3.
- 13. A method of immunizing against Neisseria meningitidis which comprises administering to a human host an immunogenic amount of the vaccine composition of Claim 2.
- 14. A method of immunizing against Neisseria meningitidis which comprises administering to a human host an immunogenic amount of the vaccine composition of Claim 6.
- 15. A method for preparing a vaccine composition which comprises including an isolated and purified recombinantly-expressed pilin protein of the genus Neisseria, in an amount sufficient such that said vaccine composition elicits a protective immune response in a human host.
- 16. An isolated and purified DNA sequence comprising a DNA sequence which hybridizes under standard high stringency Southern hybridization conditions with a DNA sequence encoding the chimeric recombinant pilin protein of Neisseria gonorrhoeae and

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class I Neisseria meningitidis having the amino acid sequence of amino acids 1-167 of SEQ ID NO:2 prior to processing or having the amino acid sequence of amino acids 8-167 of SEQ ID NO:2 after processing to a mature protein, or a biologically equivalent amino acid sequence thereof.

- 17. The isolated and purified DNA sequence of Claim 16, wherein said DNA sequence hybridizes under standard high stringency Southern hybridization conditions with a DNA sequence having the nucleotide sequence of nucleotides 1-501 or 22-501 of SEQ ID NO:1.
- 18. An isolated and purified DNA sequence comprising a DNA sequence encoding the chimeric recombinant pilin protein of Neisseria gonorrhoeae and class I Neisseria meningitidis having the amino acid sequence of amino acids 1-167 of SEQ ID NO:2 prior to processing or having the amino acid sequence of amino acids 8-167 of SEQ ID NO:2 after processing to a mature protein, or a biologically equivalent amino acid sequence thereof.
- 19. A plasmid containing an isolated and purified DNA sequence comprising a DNA sequence which hybridizes under standard high stringency Southern hybridization conditions with a DNA sequence encoding the chimeric recombinant pilin protein of Neisseria gonorrhoeae and class I Neisseria meningitidis having the amino acid sequence of amino acids 1-167 of SEQ ID NO:2 prior to processing or having the amino acid sequence of amino acids 8-167 of SEQ ID NO:2 after processing to a mature protein, or a biologically equivalent amino acid sequence thereof.
- 20. The plasmid of Claim 19 wherein the plasmid contains a DNA sequence which hybridizes under standard high stringency Southern hybridization

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conditions with a DNA sequence having the nucleotide sequence of nucleotides 1-501 or 22-501 of SEQ ID NO:1.

- 21. A plasmid containing an isolated and purified DNA sequence encoding a chimeric recombinant pilin protein of Neisseria gonorrhoeae and class I Neisseria meningitidis comprising the DNA sequence of Claim 18.
- 22. The plasmid of Claim 21 wherein the plasmid is that designated pPX2004 (ATCC 98637).
- 23. A host cell transformed with the plasmid of Claim 19.
- 24. The host cell of Claim 23 wherein the host cell is an *Escherichia coli* strain.
- 25. The host cell of Claim 24 wherein the plasmid is that designated pPX2004 (ATCC 98637).
- 26. A method of producing a chimeric recombinant pilin protein of Neisseria gonorrhoeae and class I Neisseria meningitidis which comprises transforming or transfecting a host cell with the plasmid of Claim 19 and culturing the host cell under conditions which permit the expression of said chimeric recombinant pilin protein by the host cell.
- 27. An isolated and purified chimeric recombinant pilin protein of Neisseria gonorrhoeae and class I Neisseria meningitidis having the amino acid sequence of amino acids 1-167 of SEQ ID NO:2 prior to processing or having the amino acid sequence of amino acids 8-167 of SEQ ID NO:2 after processing to a mature protein, or a biologically equivalent amino acid sequence thereof.
- 28. The vaccine composition of Claim 1 where the pilin protein is a chimeric recombinant pilin protein of Neisseria gonorrhoeae and class II Neisseria meningitidis having the amino acid sequence of amino acids 1-170 of SEQ ID NO:4 prior to processing or

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having the amino acid sequence of amino acids 8-170 of SEQ ID NO:4 after processing to a mature protein, or a biologically equivalent amino acid sequence thereof.

- 29. A method of immunizing against Neisseria gonorrhoeae which comprises administering to a human host an immunogenic amount of the vaccine composition of Claim 28.
- 30. A method of immunizing against Neisseria meningitidis which comprises administering to a human host an immunogenic amount of the vaccine composition of Claim 28.
- 31. An isolated and purified DNA sequence comprising a DNA sequence which hybridizes under standard high stringency Southern hybridization conditions with a DNA sequence encoding the chimeric recombinant pilin protein of Neisseria gonorrhoeae and class II Neisseria meningitidis having the amino acid sequence of amino acids 1-170 of SEQ ID NO:4 prior to processing or having the amino acid sequence of amino acids 8-170 of SEQ ID NO:4 after processing to a mature protein, or a biologically equivalent amino acid sequence thereof.
- 32. The isolated and purified DNA sequence of Claim 31, wherein said DNA sequence hybridizes under standard high stringency Southern hybridization conditions with a DNA sequence having the nucleotide sequence of nucleotides 1-510 or 22-510 of SEQ ID NO:3.
- 33. An isolated and purified DNA sequence comprising a DNA sequence encoding the chimeric recombinant pilin protein of Neisseria gonorrhoeae and class II Neisseria meningitidis having the amino acid sequence of amino acids 1-170 of SEQ ID NO:4 prior to processing or having the amino acid sequence of amino acids 8-170 of SEQ ID NO:4 after processing to a mature

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protein, or a biologically equivalent amino acid sequence thereof.

- 34. A plasmid containing an isolated and purified DNA sequence comprising a DNA sequence which hybridizes under standard high stringency Southern hybridization conditions with a DNA sequence encoding the chimeric recombinant pilin protein of Neisseria gonorrhoeae and class II Neisseria meningitidis having the amino acid sequence of amino acids 1-170 of SEQ ID NO:4 prior to processing or having the amino acid sequence of amino acids 8-170 of SEQ ID NO:4 after processing to a mature protein, or a biologically equivalent amino acid sequence thereof.
- 35. The plasmid of Claim 34 wherein the plasmid contains a DNA sequence which hybridizes under standard high stringency Southern hybridization conditions with a DNA sequence having the nucleotide sequence of nucleotides 1-510 or 22-510 of SEQ ID NO:3.
- 36. A plasmid containing an isolated and purified DNA sequence encoding a chimeric recombinant pilin protein of Neisseria gonorrhoeae and class II Neisseria meningitidis comprising the DNA sequence of Claim 33.
- 37. The plasmid of Claim 36 wherein the plasmid is that designated pPX8017 (ATCC 207199).
- 38. A host cell transformed with the plasmid of Claim 34.
- 39. The host cell of Claim 38 wherein the host cell is an Escherichia coli strain.
- 40. The host cell of Claim 39 wherein the plasmid is that designated pPX8017 (ATCC 207199).
- 41. A method of producing a chimeric recombinant pilin protein of Neisseria gonorrhoeae and class II Neisseria meningitidis which comprises transforming or transfecting a host cell with the

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plasmid of Claim 34 and culturing the host cell under conditions which permit the expression of said chimeric recombinant pilin protein by the host cell.

42. An isolated and purified chimeric recombinant pilin protein of Neisseria gonorrhoeae and class II Neisseria meningitidis having the amino acid sequence of amino acids 1-170 of SEQ ID NO:4 prior to processing or having the amino acid sequence of amino acids 8-170 of SEQ ID NO:4 after processing to a mature protein, or a biologically equivalent amino acid sequence thereof.